

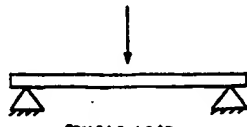

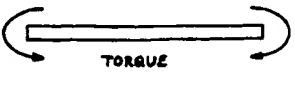





## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification <sup>6</sup> : <b>A61M</b></p>	<p><b>A2</b></p>	<p>(11) International Publication Number: <b>WO 98/22159</b></p> <p>(43) International Publication Date: 28 May 1998 (28.05.98)</p>
<p>(21) International Application Number: PCT/US97/20695</p> <p>(22) International Filing Date: 7 November 1997 (07.11.97)</p> <p>(30) Priority Data: 60/029,936 7 November 1996 (07.11.96) US</p> <p>(71) Applicant (for all designated States except US): MEDTRONIC INSTENT INC. [US/US]; 6271 Bury Drive, Eden Prairie, MN 55346 (US).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): GLOBERMAN, Oren [IL/IL]; Yericho 14, 58543 Holon (IL). BEYAR, Mordechay [IL/IL]; Haeshcolit Street 5, 38900 Caeseria (IL). BEYAR, Rafael [IL/IL]; Watson Street 8, 34751 Haifa (IL).</p> <p>(74) Agents: DIPPERT, William, H. et al.; Cowan, Liebowitz &amp; Latman, P.C., 1133 Avenue of the Americas, New York, NY 10036-6799 (US).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b> Without international search report and to be republished upon receipt of that report.</p>
<p>(54) Title: VARIABLE FLEXIBILITY STENT</p> <p>(57) Abstract</p> <p>A stent is provided for having variable flexibility and stiffness along its length. The stent comprises portions of the stent having different bending and durability characteristics, and may be fabricated, using any of a variety of methods, out of any of a variety of materials.</p> <div style="display: flex; justify-content: space-around; align-items: flex-start;"> <div style="text-align: center;"> <p><u>LOADING CONDITIONS</u></p>  <p>UNIFORM LOAD</p> <p>a</p> </div> <div style="text-align: center;"> <p><u>BENDING MOMENT GRAPHS</u></p>  <p>MOMENT DIAGRAM ALONG THE STENT</p> <p>b</p> </div> </div> <div style="display: flex; justify-content: space-around; align-items: flex-start; margin-top: 20px;"> <div style="text-align: center;">  <p>SINGLE LOAD</p> <p>c</p> </div> <div style="text-align: center;">  <p>MOMENT DIAGRAM ALONG THE STENT</p> <p>d</p> </div> </div> <div style="display: flex; justify-content: space-around; align-items: flex-start; margin-top: 20px;"> <div style="text-align: center;">  <p>TORQUE</p> <p>e</p> </div> <div style="text-align: center;">  <p>MOMENT DIAGRAM ALONG THE STENT</p> <p>f</p> </div> </div>		

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakhstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

-1-

## VARIABLE FLEXIBILITY STENT

FIELD OF THE INVENTION

This invention concerns a novel stent. More particularly, this invention concerns a stent having variable flexibility and stiffness.

5

BACKGROUND OF THE INVENTION

A common characteristic of many stents in the market is longitudinal axis symmetry. Some of the stents, such as the Medtronic WIKTOR™ stents and the Medtronic InStent CARDIOCOIL™  
10 stents, have a spiral structure. Such spiral structures have a cyclic helical coil element called "pitch." Other stents, such as the ACS MULTILINK™ stent, the Johnson & Johnson PALMAZ-SCHATZ™ stent, and the Medtronic Instant beSTENT™, are designed with a cyclic mesh element. Further stents such as  
15 the Johnson & Johnson Articulated Stent and the NIR stent have a double cyclic structure, that is, odd and even longitudinal elements where an odd element comes after an even element, and all the odd elements are identical and all the even elements are identical.

20 All the above stents have in common the characteristic of the uniformity of flexibility or durability for bending along the length of the stent.

Tests done on long stents loaded with bending stresses reveal a large bending moment in the central area of the  
25 stent. (See, for example, Figs. 1a-1f.) Such stresses may cause fatigue and even fracture at the center of the stent. On the one hand, significant stent flexibility is required during deployment while, on the other hand, significant rigidity is required in the expanded state of the stent.  
30 Since the bending moment increases from zero at the ends of the stent to a maximum value at the center, it has been

-2-

determined that there is a need for a stent having a significant durability for bending at the exact place where the durability is required, that is, at the middle of the stent.

5

#### OBJECTS OF THE INVENTION

It is an object of this invention to provide a novel stent which does not have the disadvantages inherent in known stents.

10 It is also an object of this invention to provide a stent having variable flexibility and/or durability and/or stiffness.

It is further object of the invention to provide a stent having a large or significant durability for bending, i.e.,  
15 rigidity or stiffness, at the middle portion of the stent.

These and other objects of the invention will become apparent to one skilled in the art from the discussion below.

#### SUMMARY OF THE INVENTION

20 The present invention provides for a novel stent which overcomes many of the disadvantages associated with various prior art stent designs which rely upon a stent construction which provides for a uniformly rigid construction or a uniform alternating rigid/less rigid construction. The invention  
25 provided for herein is directed to a stent having variable flexibility and moment along its length. The stent comprises portions of the stent having different bending and durability characteristics, as designed. In one embodiment of the invention, the members of the stent have components that have  
30 been designed to impart different load characteristics.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Figs. 1a-1f are diagrams of loading studies of various stents;

-3-

Fig. 2 is an oblique view of one embodiment of the invention; and

Fig. 3 is a plan view of another embodiment of the invention.

5

#### DESCRIPTION OF THE PREFERRED EMBODIMENT

The invention can perhaps be better appreciated by making reference to the drawings. In Fig. 2, a stent 1 is positioned on the outer surface of a catheter 3. Stent 1 in this  
10 embodiment comprises a mesh lattice construction having sections 5, 7, 9, 11, 13, and 15 which are of varying degrees of flexibility or stiffness. For example, end sections 5 and 15 are comprised of smaller diameter and, therefore, less rigid mesh, inner sections 7 and 13, are comprised of larger  
15 diameter and more rigid mesh, and center sections 9 and 11 are comprised of even larger diameter and still more rigid mesh.

Annular cross members 19 are shown in Fig. 2 to be substantially similar in size, both in length and cross-section. However, it is within the scope of the invention  
20 that cross members 19 can vary in size, especially cross-section, and impart different rigidity to stent 1. Similar to the discussion above for sections 5, 7, 9, 11, 13, and 15, cross members 19 could have a larger cross-section near the middle of stent 1 and increas-ingly smaller cross-sections  
25 toward the ends of stent 1.

Another embodiment of the invention is represented in Fig. 3 by the partial lattice-work section 31 of a balloon-expandable stent where annular members 33 expand as a dilatation balloon is expanded within the stent. Cross  
30 members 35 will continue to "link" members as the stent expands. While annular member 33 can be of similar size and rigidity, according to the invention members 33 will differ in size, e.g., thickness or even length, over the length of stent 31, to provide desired characteristics. It is anticipated  
35 that, as described before for the embodiment of Fig. 2, cross

-4-

members 35 will be more rigid toward the longitudinal center of stent 31 and less rigid toward the ends.

The actual dimensions of stents according to the invention will vary dependent upon intended use and the characteristics to be imparted. For example, for a stent intended for cardiovascular use and having an expanded length of from about 3 to 10 cm, the annular members and/or cross members may each have a cross-sectional profile of from about 0.01 to 0.10 cm, varying as discussed above.

10 The stents according to the invention can be comprised of a variety of materials known to be useful in fabricating stents, such as stainless steel, nitinol, tantalum, and/or other metals or alloys. If the stent is a mesh, the mesh can be formed, stamped, or etched to vary the size and/or diameter of the mesh components. Alternatively, the mesh could be 15 formed from component members of different diameters that are soldered or welded together. Fabrication is discussed more below.

It is within the scope of the invention that a stent 20 having variable stiffness could be comprised of other than a mesh. For example, a spiral coil stent could be formed from wire of variable diameter where the rigidity or stiffness of certain portions would vary according to the diameter. Preferably the end portions would be of a small diameter with 25 gradual or step increases in diameter occurring toward the center of the stent.

A primary characteristic of stents according to the invention is that the moment diagrams, such as are shown in Figs. 1a-1f, will be modified to avoid an unacceptable load, 30 or peak, in the middle. Thus, in the stents according to the present invention the load will be distributed more evenly across the entire length of the stent.

The manufacture of stents according to the presentation invention may be accomplished via any of a variety of methods.

-5-

In one method of fabrication of a patterned etched cylinder a wire mesh is formed from a flat planar surface and then its two opposite edges are fused to create a cylinder. This method, however, suffers a basic disadvantage in that the presence of the fusing line creates a weakened area along the longitudinal axis of the stent, which is potentially subject to fatigue and breakage. Therefore, it is preferable for the stent to be formed from a more uniform piece of material to avoid this potential problem.

There are also two alternative methods for imaging the desired pattern, i.e., the location of points, undulating connectors, ring and connecting segments, etc., as may be required by a particular stent design onto a continuous cylinder, without the need of fusing into a cylinder after forming of the design. These methods, a film contact imaging method and a laser scanning method, are disclosed in co-pending U.S. patent application Serial No. 08/543,337, filed October 16, 1995, the teachings of which are incorporated herein by reference.

As has been described in more detail in said co-pending application, the film contact imaging method is carried out using an elliptical mirror which reflects ultraviolet light from an ultraviolet light source. The ultraviolet light source is located at one focal point of the elliptical mirror and illuminates through a slit of narrow aperture (which eliminates scattered light). The slit or aperture is located at the other focal point of the elliptical mirror to allow for high density power illumination from the ultraviolet source. Rays of ultraviolet light are thus reflected off of the elliptical mirror to pass through the slit or aperture and onto a moving film. The slit extends parallel to the longitudinal axis of a hollow tube or cylinder. The film carries the design sought to be provided onto the surface of the tube or cylinder.

The film is in contact with the hollow cylinder. The hollow cylinder is made of material which is to be fabricated

-6-

into the stent of the present invention. The film serves as a mask or template, being transparent to ultraviolet light in some areas and opaque to ultraviolet light in others in the predefined stent pattern. The cylinder is coated with an appropriate material (a photoresist) for a photo-etching process. As ultraviolet light is transmitted onto the film through the slit, the film moves past the cylinder while the cylinder rotates. The rotation of the cylinder is correlated with the movement of the film to appropriately image the pattern on the film around and onto the cylinder. As a result, ultraviolet light passing through UV-transparent portions of the film template will strike the cylinder in the desired pattern to photoetch the appropriate configuration onto the cylinder. An acid treatment is then used to remove the areas which were struck by the UV light. In general, the chemical aspects of the system are similar to that used in the manufacturer of computer chips, i.e., photoresist, masking, acid, etc.

It should be pointed out that variations on this design will be understood by those of ordinary skill in the art. For example, in the presence of a sufficiently high powered light source, usage of an elliptical mirror is not essential.

The second, and preferred, method, which is also described in more detail in said co-pending application, uses a laser scanning system. The system consists of a cylinder or tube to be etched, a laser, the laser optics (containing beam components and modulator), and a dynamic deflector (such as a rotating mirror, a polygon, or any other known scanning deflector). The system is based upon a well-known flat bed scanning system. The cylinder is coated with a photoresist, or material suitable for photoetching. A laser is selected of the appropriate power and wavelength suitable for stimulating the photoresist in use. For example, for an ablation method, the laser can be high powered IR laser diode; for a photoresist sensitive to visible light, the laser can be a laser in the visible range or for a conventional UV photoresist, an Eximer laser or third (or higher) harmonic



-7-

generation Nd:YAG/Nd:YLF laser can be used. The laser beam is shaped by an appropriate optical system, and modulated by direct modulation in the case of an IR laser diode, with AOM (an Acoustic Optical Modulator) in the case of a CW laser in the visible, or by a vibrating mirror in the case of a UV laser.

The laser beam from the laser hits a deflector device which can be a rotating mirror, a polygon mirror, or other known scanning device. The beam emerges from the deflector, passing through a scan lens and is focused on the cylinder. The cylinder, which is coated with a photoresist, rotates about its longitudinal axis at a constant angular velocity, while the beam scans back and forth. The modulation of the laser beam allows writing a computer imaging file directly on the cylinder without the need of intermediate media (e.g. film). The laser scanning velocity is correlated to the cylinder angular velocity, and is determined by the energy required for exposure of the photoresist.

It is contemplated that the stents according to the present invention may also be fabricated by any of a variety of other methods and techniques available to the art without departing from the spirit or scope of the invention.

It is also contemplated that the stents of the present invention may be constructed in any of a number of configurations and arrangements known in the art so long as the primary requirement of the invention is met, that being that the stent be constructed in such a manner that the end product stent is provided with a varying degree of flexibility and stiffness along the length of the stent.

It will thus be seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained and, since certain changes may be made in the constructions set forth without departing from the spirit and scope of the invention, it is intended that all matter contained in the above description and shown in the

-8-

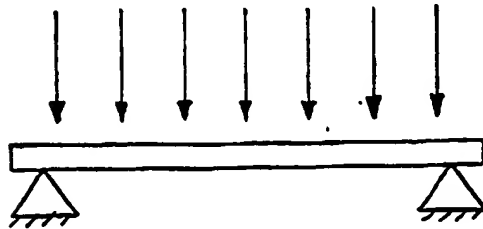
accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention herein described and all statements of the scope  
5 of the invention which, as a matter of language, might be said to fall therebetween.

WHAT IS CLAIMED IS:

1. A stent having variable bending flexibility across its length.
2. The stent of Claim 1, wherein the stent is comprised of component members having variable dimensions to vary the stiffness of the stent in the longitudinal direction.
3. The stent of Claim 1, wherein the stent is comprised of component members having variable composition to vary the stiffness of the stent in the longitudinal direction.
4. The stent of Claim 1, wherein the stent is relatively less rigid for bending at its ends and relatively more rigid for bending in its center.
5. The stent of Claim 1, which is comprised of a mesh.
6. The stent of Claim 1, which is comprised of a spiral coil.
7. The stent of Claim 1, which is fabricated out of a material selected from the group comprising stainless steel, nitinol, titanium, tantalum, and other metals and metal alloys.
8. The stent of Claim 1, which has been fabricated by a method selected from the group comprising forming, stamping and etching.
9. The stent of Claim 1, which has been fabricated using a film contact imaging method.
10. The stent of Claim 1, which has been fabricated using a laser cutting method.
11. A stent having variable flexibility across its length, which comprises a tubular member consisting essentially of annular members intended to expand and cross member having ends, the end of each cross member being attached to an annular member,  
  
wherein the cross members have differing rigidity for bending such that the stent has variable flexibility along its length.

LOADING CONDITIONS



UNIFORM LOAD

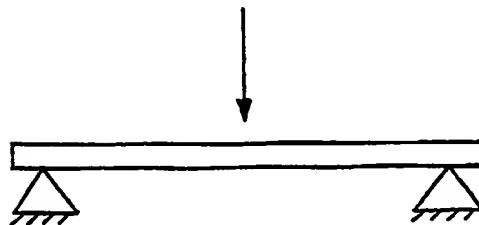
Fig. 1a

BENDING MOMENT GRAPHS



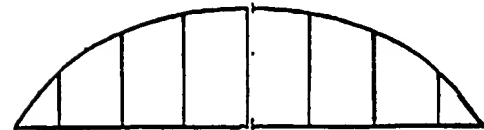
MOMENT DIAGRAM  
ALONG THE STENT

Fig. 1b



SINGLE LOAD

Fig. 1c



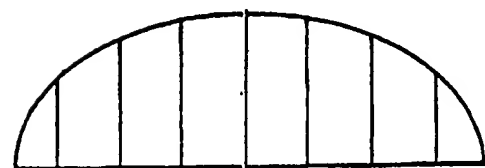
MOMENT DIAGRAM  
ALONG THE STENT

Fig. 1d



TORQUE

Fig. 1e



MOMENT DIAGRAM  
ALONG THE STENT

Fig. 1f

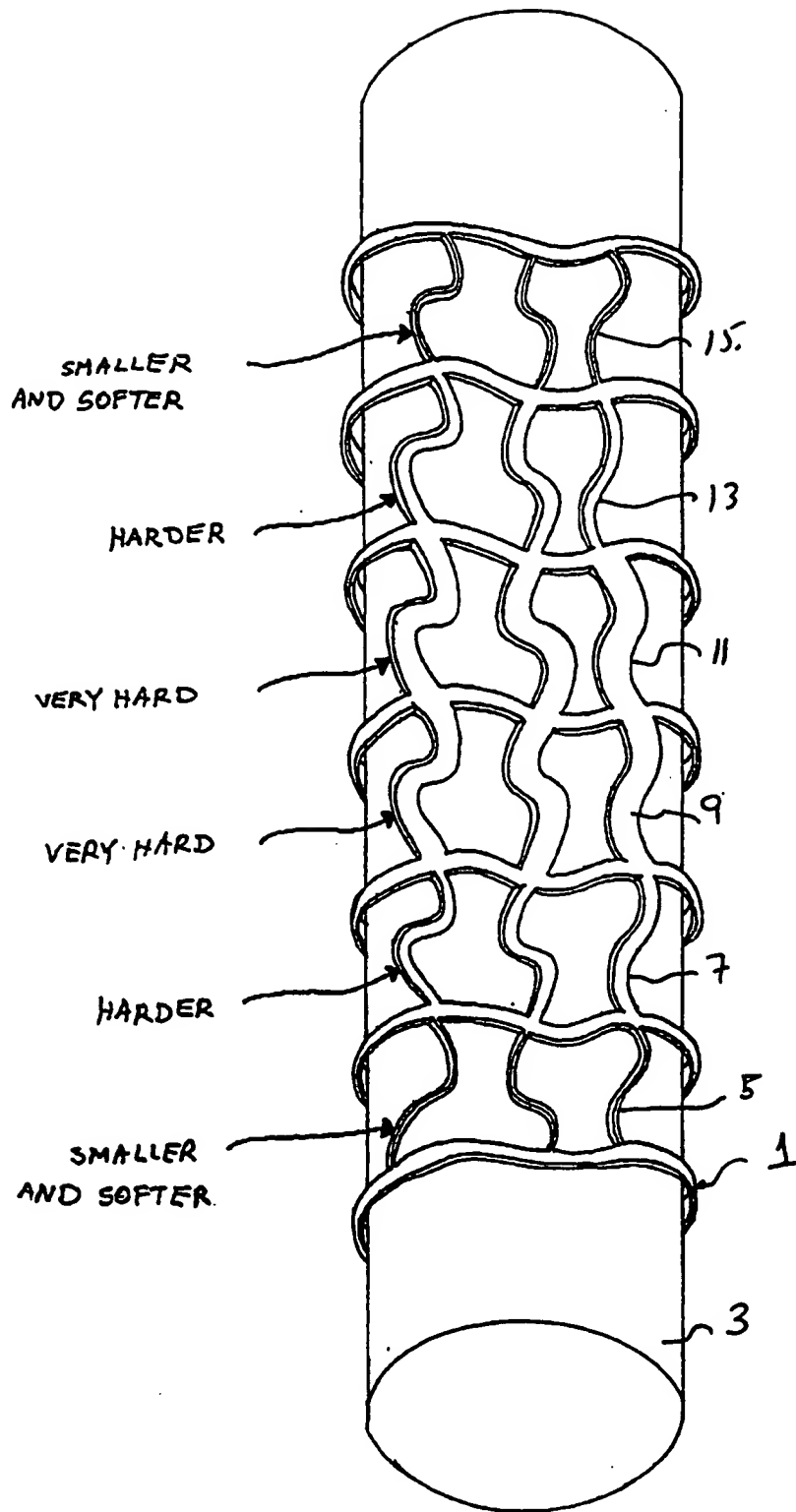


Fig. 2

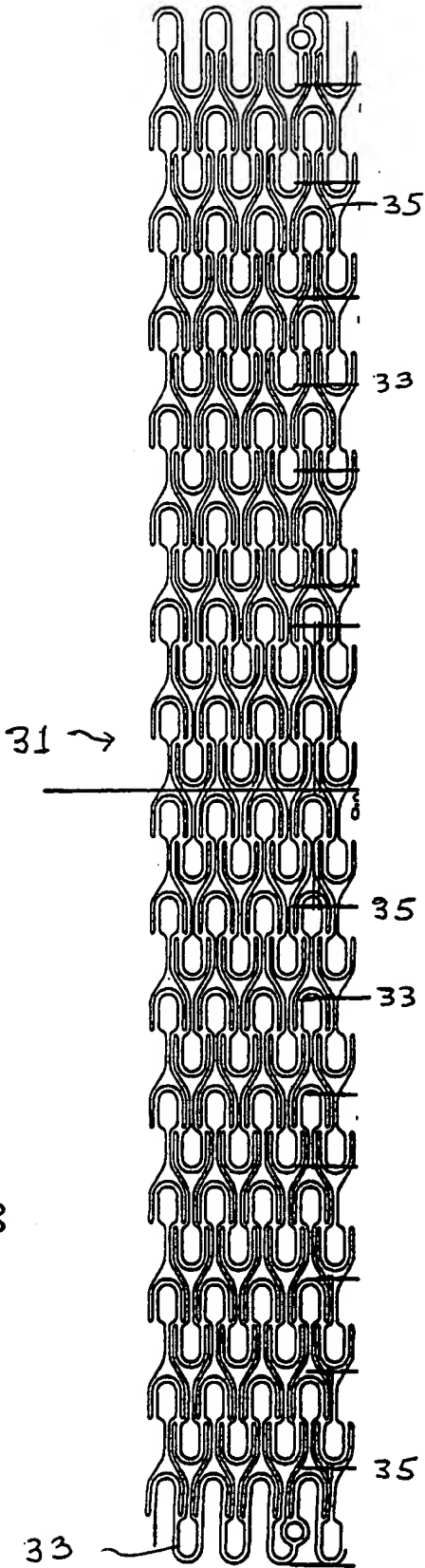


Fig. 3